

### REMARKS

This document is submitted in response to the Office Action dated September 26, 2007 ("Office Action"). Claims 1-30, 32-35, 37-40, and 42 are pending. Claims 1-26, 30, 35, 40, and 42 have been withdrawn and claims 27-29, 32-34, and 37-39 are under examination. Reconsideration is requested in view of the remarks below.

Claims 27-29, 32-34, and 37-39 were rejected for obviousness over US Patent Application Publication 2003/0139363 by Kay *et al.* ("the '363 application") in view of US Patent No. 6709812 to Stuyver *et al.* ("Stuyver"), Goodarzi *et al.*, Journal of General Virology, 1990, 71:3021-3025 ("Goodarzi"), and Welch *et al.*, Gene Therapy, 1997, 4:736-34 ("Welch"). See the Office Action, page 3, last paragraph. Applicants respectfully traverse.

The claims cover methods of inhibiting the replication of a virus in a cell or treating an infection with a virus, using an RNA or a DNA vector that contains a nucleic acid encoding the RNA. The methods include introducing into the cell an effective amount of an RNA or a DNA vector containing a nucleic acid encoding the RNA. The RNA comprises a first nucleotide sequence that hybridizes under stringent conditions to a segment of the gene, and a second nucleotide sequence that is complementary to the first nucleotide sequence and hybridizes to the first nucleotide sequence to form a duplex structure. The segment has the sequence of SEQ ID NO:3, which is an HBV sequence.

According to the Examiner, the '363 application "teaches a method of reducing HBV expression and HBV viral replication in mammalian cells [and] mice by introducing an expression vector comprising an shRNA targeted to HBV RNA sequence." She admitted that the '363 application did not teach SEQ ID NO: 3, but asserted that the other cited references rectified this defect.

The '363 application was published July 24, 2003, which is after the effective filing date of the present application, i.e., December 3, 2002. As the '363 application was filed September 27, 2002, it seems that the Examiner cited it as prior art under §102(e). The '363 application is a continuation-in-part (CIP) application of another US Patent

Application, 10/259,226 ("the '226 application"). The latter was filed on July 19, 2002 and subsequently published as US 20030153519.

Applicants submit that, as prior art, the '363 application is not entitled to the July 19, 2002 date. As the Examiner is aware, "the subject matter relied upon in the rejection must be disclosed in the earlier-filed application in compliance with 35 U.S.C. 112, first paragraph, in order to give that subject matter the benefit of the earlier filing date under 35 U.S.C. 102(e)." See MEPE 2136.03. Applicants have noticed that the '226 application did NOT mention "HBV" at all, much less "a method of reducing HBV expression and HBV viral replication in mammalian cells [and] mice by introducing an expression vector comprising an shRNA targeted to HBV RNA sequence." Thus, as far as the HBV-related teaching is concerned, the '363 application is not entitled to the July 19, 2002 date. To the contrary, the effective prior art date is its actual filing date, September 27, 2002.

In this connection, Applicants would like to point out that the '363 application does not qualify as prior art under §102(e). In the previous office action, the Examiner raised a §102(e) novelty rejection based on Morrissey *et al.*, US Patent Application Publication 2003/0206887 ("Morrissey"). Morrissey has a prior art date of September 16, 2002. In response, Applicants submitted a declaration and presented evidence showing that the claimed method was invented prior to September 16, 2002. Applicants accordingly argued that Morrissey does not qualify as prior art. The Examiner agreed and withdrew the novelty rejection. Since September 16, 2002 is prior to September 27, 2002 (the prior art date of the '363 application), the '363 application, like Morrissey, does not qualify as prior art under §102 (e) either.

Therefore, Applicants submit that all of the claims are patentable over the cited references and the rejection should be withdrawn.

The obviousness rejection can also be rebutted by a showing of an unexpected result. Such an unexpected result is a secondary factor considered under the Graham Factual Inquiries as set forth in *Graham v. John Deere Co.* See MEPE 2141. As disclosed in the specification, an RNA having a sequence corresponding to SEQ ID NO:

3 or a DNA vector that contains a nucleic acid encoding the RNA inhibited HBsAg expression by an unexpected level of 99%. See, e.g., page 6, lines 14-22, and page 5, lines 15-22. Note that, according to MPEP2144, such a, rebuttal evidence can be presented in the specification.<sup>1</sup> Thus, the claims are not obvious on this independent ground.

In view of the above remarks and unexpected result, Applicants submit that the claims are patentable.

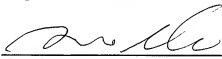
### Conclusion

It is believed that all of the pending claims have been addressed. However, the absence of a reply to a specific rejection, issue or comment does not signify agreement with or concession of that rejection, issue or comment. In addition, because the arguments made above may not be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed. Finally, nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper, and the amendment of any claim does not necessarily signify concession of unpatentability of the claim prior to its amendment.

Please apply any other charges or credits to Deposit Account No. 50-4189, referencing Attorney Docket No. 70001-020001.

Respectfully submitted,

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Jianming Hao, Ph.D.  
Reg. No. 54,694

Customer No. 69713  
Occhiuti Rohlicek & Tsao LLP  
10 Fawcett Street  
Cambridge, MA 02138  
Telephone: (617) 500-2507  
Facsimile: (617) 500-2499  
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<sup>1</sup> According to MPEP2144.08 IIB, rebuttal evidence and arguments can be presented in the specification, *In re Soni*, 54 F.3d 746, 750, 34 USPQ2d 1684, 1687 (Fed. Cir. 1995), by counsel, *In re Chu*, 66 F.3d 292, 299, 36 USPQ2d 1089, 1094-95 (Fed. Cir. 1995).